

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0151V
UNPUBLISHED

N.B.,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 19, 2022

Special Processing Unit (SPU);
Table Injury Dismissal; Tetanus,
Diphtheria, acellular Pertussis (Tdap)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA);
Onset of Shoulder Pain

Kathleen Margaret Loucks, Lommen Abdo Law Firm, Minneapolis, MN, for Petitioner.

Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW **DISMISSING TABLE CLAIM¹**

On February 13, 2020, N.B. filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleged that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table Injury, after receiving a tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine on August 9, 2018. Petition at ¶¶ 1-3. She further alleged that she experienced pain and discomfort within 48 hours of vaccination. *Id.* at ¶ 5.

¹ When this unpublished Fact Ruling was originally filed, I advised my intent to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), Petitioner filed a timely motion to redact certain information. This Fact Ruling is being posted with Petitioner's name redacted to reflect initials only and the redaction of her specific area of legal practice and son's first name. Except for those changes and this footnote, no other substantive changes have been made. This Fact Ruling will be posted on the court's website with no further opportunity to move for redaction.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, a preponderance of the evidence supports the conclusion that the onset of Petitioner's left shoulder pain occurred *later* than 48 hours post-vaccination – meaning she cannot establish the onset required for her Table SIRVA claim, and therefore the Table claim must be dismissed. And a causation-in-fact version of the claim can only go forward if Petitioner provides additional supporting evidence not yet offered in the case.

I. Relevant Procedural History

The day after filing the Petition, N.B. filed an affidavit and medical records required by the Vaccine Act. Exhibits 1-12, ECF No. 7; see Section 11(c). The case was activated and assigned to SPU. ECF No. 10.

During the initial status conference, held on April 16, 2020, the parties discussed evidence which appeared contrary to Petitioner's claim of pain onset within 48 hours. Order, issued Apr. 17, 2020, at 1-2, ECF No. 14. Respondent also raised the fall Petitioner experienced in February 2018 – approximately six months prior to vaccination - as a further complicating factor. *Id.* at 2. On July 2, 2020, Petitioner filed additional evidence addressing these issues and the question of causation – a letter from the second orthopedist seen approximately one-year post-vaccination, corrections to medical records made approximately two years post-vaccination and one request which was denied, and signed declarations³ from her husband, three of her children, a paralegal at her law firm,⁴ and herself. Exhibits 13-22, ECF No. 15.

On June 29, 2021, Respondent filed his Rule 4(c) Report opposing compensation in this case. ECF No. 25. Specifically, Respondent argued that Petitioner “has not provided preponderant evidence that the onset of her symptoms occurred within 48 hours of vaccination.” *Id.* at 9; *accord.* at 9-12. He also stressed that the medical records show Petitioner did not attribute her left shoulder pain to the Tdap vaccine until July 2019 – eleven months post-vaccination (*id.* at 10-11) - and further admitted that she did not relate her shoulder pain to this vaccination until she read an article on SIRVA that was provided by her attorney (*id.* at 11).

³ These declarations are signed under penalty of perjury in accordance with 28 U.S.C.A. § 1746. Although Petitioner previously provided a notarized affidavit (Exhibit 4), this filing is her first signed declaration. Exhibit 17. Additionally, these statements are the first signed declarations for her husband, children, and co-worker. Exhibits 18-22. Petitioner's husband later provided a second signed declaration. See *infra* note 5.

⁴ Petitioner is an attorney. *E.g.*, Exhibit 17 at ¶ 1 (Petitioner's first signed declaration).

In reaction, Petitioner filed supplement declarations⁵ from her husband and herself alleging that she had experienced pain on the night of vaccination, a note from her primary care provider (“PCP”) clarifying the date of vaccination, and a motion for a ruling on the record as it currently stood. Exhibits 25-26, filed Aug. 26, 2021, ECF No. 27; Exhibit 27, filed Aug. 30, 2021, ECF No. 29; Motion Petitioner’s Motion for a Ruling on the Record (“Motion”), filed Aug. 31, 2021, ECF No. 31. During September 2021, Respondent filed a response, and Petitioner filed medical literature and a reply. Response to Motion (“Response”), filed Sept. 14, 2021, ECF No. 32; Exhibits 28-29, filed Sept. 21, 2021, ECF No. 33; Petitioner’s Reply (“Reply”),⁶ filed Sept. 21, 2021, ECF No. 35.

II. Issue

At issue is whether Petitioner’s first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation (“QAI”) for a Table SIRVA. 42 C.F.R. § 100.3(a) I.C. & II.C. (2017) (Tdap vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner’s injury or illness that is contained in a medical record. Section 13(b)(1). “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.” *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-

⁵ Like those filed in July 2020 (see *supra* note 3), these declarations are signed under penalty of perjury in accordance with 28 U.S.C.A. § 1746. Exhibits 25-26. They will be referred to herein as the second signed declarations of Petitioner and her husband.

⁶ Because she filed her reply as a memorandum, Petitioner filed a motion to strike and refiled her reply. Motion to Strike, filed Sept. 21, 2021. However, in subsequent email communications with the parties, she was informed this correction was not needed. See Informal Remark, dated Oct. 5, 2021. The motion to strike was deemed moot and was terminated. See Non-pdf Order, issued Oct. 5, 2021.

1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. “Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery v. Sec’y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical

records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Relevant Factual Evidence

The medical records show that Petitioner did not experience any left shoulder pain, injury, or dysfunction prior to vaccination. Petitioner suffered from osteoporosis, asthma, abdominal pain, hypothyroidism, and common breast lumps. Exhibit 8 at 10-56. She also complained of left sided chest pain in early February 2018, following a fall on her left side while walking up some bleachers in Sweden. Exhibit 9 at 13. Although Respondent initially questioned whether Petitioner's later left shoulder pain could be attributed to this fall, he did not raise the issue again in his Rule 4(c) Report, and Petitioner addressed this issue in additional filings. See Exhibit 17 at ¶ 6 (Petitioner's first signed declaration), 10-32 (diary entries); Exhibit 19 at ¶ 5 (a son's signed declaration).

The evidence regarding the onset and cause of Petitioner's left shoulder pain is less clear, however, even after Petitioner provided additional evidence on several occasions. Thus, I will discuss this evidence as provided.

1. Initially Provided Evidence

Petitioner received the Tdap vaccine alleged as causal on August 9, 2018, when seen for a laceration on her foot after stepping on a piece of plastic. Exhibit 1 at 9 (vaccine record); Exhibit 8 at 57-60 (record from August 9th visit). Later that day, Petitioner spoke to clinic personnel by phone, expressing her frustration at having received a Tdap vaccine, as opposed to a tetanus-only vaccine. Exhibit 8 at 61-64. There is no mention of any left shoulder pain in these medical records from that day.

In her affidavit, Petitioner stated that she did not feel unusual pain at the time of vaccination, but did have pain within 48 hours. Exhibit 4 at ¶ 4. However, during the four months post-vaccination, Petitioner sought treatment on multiple occasions without once mentioning any left shoulder pain. For example, she returned to her PCP on November 9, 2018, complaining of a two-week history of blisters on her lips - described as "sometimes painful and irritating," increased itching and intermittent pain in her eyes, and mild swelling of her ankles. Exhibit 8 at 65. Although first seen by a medical student at this visit, Petitioner's PCP indicated that she "personally performed the exam and medical decision making and agree[d] with the student's documentation." *Id.* at 68. Later in November, Petitioner saw her ophthalmologist for her eye issues and endocrinologist for a check-up. Exhibit 5 at 28-36; Exhibit 6 at 26-28. Again, there is no mention of left shoulder pain in the records from these visits. *Id.*

Petitioner first complained of left shoulder pain at her annual physical with her PCP on December 21, 2018 – more than four months post-vaccination. Exhibit 8 at 81. As originally filed,⁷ the medical record from this visit indicated that Petitioner reported pain that had been present for a few weeks - placing onset in late November or early December 2018. She described her pain as intermittent - lasting only a few minutes. Petitioner added that she also had intermittent cramps in her feet and did not drink much water. *Id.* She did not mention the Tdap vaccine she had received in early August 2018 at this visit. *Id.* at 81-85. Petitioner was provided a handout with exercises for shoulder bursitis. *Id.* at 85.

In her affidavit, Petitioner insisted that she did not seek treatment for her left shoulder pain prior to December 21, 2018, because she was traveling with her daughter and that her appointments during this time were with her ophthalmologist and endocrinologist. Exhibit 4 at ¶ 4. However, this statement ignores the November 9th visit to her PCP. Petitioner also maintained that when she described her left shoulder pain to her PCP in December 2018, she reported that she had been suffering from this pain for months, rather than weeks as reflected in that record. Exhibit 4 at ¶ 5; see Exhibit 8 at 81.

In late February 2019, Petitioner visited an orthopedist, complaining of left shoulder pain for the last three months – again placing onset *months after* vaccination (in late November 2018 rather than August). Exhibit 11 at 5. Observed as having full strength and range of motion (“ROM”), Petitioner chose to forego a steroid injection and begin physical therapy (“PT”). *Id.* at 6. Petitioner “denie[d] any direct injury or previous surgery or radiculopathy” (*id.* at 5), and made no mention of the Tdap vaccine she had received. *Id.* at 5-6.

Petitioner again reported an onset of three months, plus no known cause for her left shoulder pain, at her first PT session on March 4, 2019. Exhibit 11 at 13. She described her pain as “intermittent and worsen[ing] as the day progresses.” *Id.* At her next PT session on March 11th, Petitioner reported compliance with her home exercise program despite being sick with the flu. *Id.* at 15. She reported additional soreness which she attributed to the bed at her vacation rental at her April 1st session. *Id.* at 17. These PT records do not contain any mention of the Tdap vaccine Petitioner received in August 2018. *Id.* at 13-19.

When Petitioner sought treatment at an urgent care facility on April 10, 2019, for a headache and nausea, she also mentioned her “troubles with her left shoulder pain for

⁷ As discussed later in this fact ruling, Petitioner requested and obtained a correction to this medical record, as well as one other, in May and June 2020. See *infra* Discussion in Section IV.2.

the last several months.” Exhibit 9 at 20. It was noted that she had been diagnosed with bursitis and was enrolled in PT. *Id.*

Petitioner saw her orthopedist several more times in April 2019, undergoing an MRI on April 19th. Exhibit 11 at 7-12. The MRI revealed no evidence of a rotator cuff tear but evidence of adhesive capsulitis - mild tendinosis, joint effusion, and bursitis. *Id.* at 9-12. Noting that a steroid injection was still a treatment option, the orthopedist indicated that Petitioner chose to continue PT. *Id.* at 10.

The first record entry mentioning the Tdap vaccine as a possible cause for Petitioner’s left shoulder pain is from a visit to Petitioner’s PCP on July 10, 2019 – almost a year after the vaccination at issue. Exhibit 6 at 35-36. This record shows the PCP noted that an August 2017 Tdap shot (with the year a likely typographical error) was administered in the same arm (*id.* at 35), and questioned whether the two were related (*id.* at 36).

When seen by a different orthopedist on August 26, 2019, Petitioner “report[ed] an initial onset of symptoms almost 1 year ago following a TDAP shot.” Exhibit 7 at 36. The orthopedist stated that he had reviewed Petitioner’s April 19th MRI (*id.*), but there is nothing to indicate he was provided with any other medical records such as those containing the earlier provided histories. *Id.* at 36-42. Agreeing with the diagnosis of adhesive capsulitis, this second orthopedist recommended Petitioner continue her PT and undergo a fluoroscopically-guided injection if her symptoms continue. *Id.* at 42. Petitioner continued to seek treatment from this second orthopedist and attended PT at a different clinic – presumably one related to this new orthopedist. See Exhibit 7.

2. Evidence Provided After Onset Issue was Noted

In early July 2020, Petitioner provided additional evidence regarding the alleged onset of her pain and the fall she suffered in February 2018 - a letter from the second orthopedist, corrections to medical records, one request for a records correction which was denied, and signed declarations from her husband, three of her children, a paralegal at her law firm, and herself. Exhibits 13-22. However, much of the information provided in these additional filings is inconsistent and is contradicted by evidence in the contemporaneously created medical records.

In her first signed declaration, Petitioner maintained that she did not mention her left shoulder pain at the November 9, 2018 visit to her PCP for mouth blisters and eye pain and itching because those conditions were acute and she was not seen by her usual PCP. Exhibit 17 at ¶ 5. However, in the contemporaneously created medical record,

Petitioner described her canker sores as “*sometimes* painful and irritating.” Exhibit 8 at 65 (emphasis added). Additionally, at this visit, Petitioner also reported a concern of swelling in her ankles, mentioning that she “noticed that at the end of the day her socks leave an indent on her ankles.” *Id.*

In his first signed declaration, Petitioner’s husband described her constant and acute left shoulder pain, which he insisted she suffered beginning in the early fall 2018, prior to the November 2018 visit. Exhibit 18 at ¶¶ 3, 5-6. However, this depiction seems to undercut Petitioner’s assertion that she did not mention her left shoulder pain at the November 9th PCP visit because her mouth blisters and eye issues were more acute.

By Petitioner’s own admission, she did not realize that a vaccine could have caused her left shoulder pain until provided an article about this injury by Petitioner’s counsel. Exhibit 17 at ¶ 5. Although she did not specify the timing of this realization, it appears to have been in late April 2019 at the earliest. Petitioner indicated that she asked her first orthopedist about this possibility at her April 23, 2019 visit. *Id.* Her husband also recalled these events, but identified the date of the visit as April 19th - which was the date of Petitioner’s MRI. Exhibit 18 at ¶ 7; see Exhibit 11 at 9-12 (MRI results and April 23rd orthopedic visit thereafter). Although they both claimed the first orthopedist agreed that Petitioner’s injury could be vaccine-related, there is nothing in the medical record from the April 23rd visit to support that allegation. Exhibit 11 at 9-10.

It appears that in May and June 2020, Petitioner sought alterations to the contemporaneously created medical records from the initial treatment she pursued through early April 2019, to show an earlier onset for her left shoulder pain than what was previously reported. She obtained revised medical records from her December 21, 2018 PCP visit when she first sought treatment for her left shoulder pain and her initial visit to her first orthopedist on February 20, 2019, which reflected an earlier onset than the late November and early December onset previously identified. Exhibits 14-15. These medical records show the alterations were made in May and June 2020. Exhibit 14 at 3 (addendum noted on June 12, 2020); Exhibit 15 at 1 (record amended on May 12, 2020). There is still no mention of the Tdap vaccine in these records, and the notation of no known mechanism of injury is still contained in the orthopedist’s record. Exhibit 15 at 1.

Petitioner also submitted a request made on May 6, 2020, to the urgent care clinic where she was seen on April 10, 2019, which was denied. Exhibit 16. The specific reason for the denial was noted to be the inability of the provider to “recall the details of [the] visit with enough certainty to be able to change them.” *Id.* at 2.

The declarations provided by Petitioner's children were signed in May and June 2020 – almost two years post-vaccination. Exhibits 18-22. They described events during the spring and summer of 2018, when Petitioner showed no left shoulder issues, such as when Petitioner helped her daughter pack up and move out of the house she had rented with friends during college in May 2018, her son move into his New York City apartment in June 2018, and another son clean his apartment when visiting in July 2018. Exhibit 19 at ¶¶ 6-7, 9; Exhibit 20 at ¶¶ 3-4; Exhibit 21 at ¶ 4. One son and daughter also provided details about visits after August 2018, when they saw their mother experience left shoulder pain and difficulties. Exhibit 20 at ¶¶ 2, 5-8; Exhibit 21 at ¶¶ 5-7.

The signed declaration from the paralegal who worked with Petitioner stated that she recalled Petitioner being upset about receiving the diphtheria and pertussis vaccines when she returned to the office on August 9, 2018. Exhibit 22 at ¶ 7. She further recalled that Petitioner “started experiencing pain in her left shoulder and arm *soon after that*,” but provided no specific time frame for this information. *Id.* (emphasis added). Recalling that Petitioner attended doctor and PT appointments thereafter, the paralegal indicated she was unaware of any injury Petitioner suffered while in Sweden. *Id.* at Exhibit 22 at ¶¶ 8-9.

In her first signed declaration, Petitioner emphasized that the second orthopedist she first saw in August 2019, opined that the Tdap vaccine she received was the likely cause of her shoulder pain. Exhibit 17 at ¶ 5. Describing this orthopedist as an orthopedic surgeon and shoulder specialist, she provided a letter in which he stated his opinion regarding causation and a handout given to her by a physician's assistant who worked in his clinic, who agreed that her injury was vaccine caused. *Id.*; see Exhibit 13 (letter from the orthopedic surgeon); Exhibit 17 at 7-9 (handout). The handout distinguishes the severe and persistent SIRVA pain, noted to be rare, from the transient and mild pain in the deltoid usually experienced following vaccination. Exhibit 17 at 7. It also cites the scientific/medical article which helped to prompt the addition of SIRVA to the Vaccine Injury Table (a study of 13 cases in which 50 percent of the adults reported shoulder pain immediately upon vaccination and 90 percent developed pain within 24 hours of vaccination). *Id.*; see National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136-37 (July 29, 2015).

3. Evidence Provided with Motion

Along with her motion, Petitioner provided supplemental signed declarations from her husband and herself, containing the first descriptions of left shoulder pain the night of vaccination. Exhibits 25-26 (second signed declarations). Both declarations were signed in late August 2021. Exhibit 25 at 2; Exhibit 26 at 2. In all earlier reports of onset, Petitioner

alleged only that her left shoulder pain began within 48 hours of vaccination. See, e.g., Exhibit 4 at ¶¶ 4, 7 (affidavit provided with the Petition). Petitioner also provided a correction to the PCP medical record from July 10, 2019, which had mistakenly listed the year of the Tdap vaccine as 2017, and copies of the article⁸ previously mentioned plus another article⁹ stressing the importance of administering vaccines below the top third of the deltoid muscle. Exhibits 27-29.

V. Findings of Fact

In the Vaccine Program, contemporaneously created “[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions.” *Cucuras*, 993 F.2d at 1528 (emphasis added). The Federal Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner. When these medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie*, 2005 WL 6117475, at *20.

Before the revisions requested by Petitioner, the contemporaneously created medical records by themselves best supported the conclusion that Petitioner began to experience left shoulder pain no sooner than late November or early December 2018 – months after the August 2018 vaccination. Exhibit 8 at 81; Exhibit 11 at 5; Exhibit 11 at 13; Exhibit 9 at 20 (in chronological order). In these early histories given to four different providers in December 2018 through April 2019, Petitioner provided the same, consistent description for the onset of her pain. She also described her pain as intermittent – lasting for only a few minutes to her PCP in December 2018. Exhibit 8 at 81. And in all medical records, Petitioner failed to mention any connection to the Tdap vaccine she received in August 2018. In fact, it was sometimes noted that there was no known cause for Petitioner’s pain. See, e.g., Exhibit 11 at 13.

By Petitioner’s own admission, she did not attribute her left shoulder pain to the Tdap vaccine she received in August 2018 until provided medical literature regarding SIRVA injuries by her attorney. Exhibit 17 at ¶ 5. It is illogical to believe that Petitioner would not have made this connection herself if she had experienced the timely onset of left shoulder pain that she now claims. Indeed, Program claimants routinely report to treaters (often close-in-time to vaccination) that they not only feel pain but that it began

⁸ S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 Vaccine 8049 (2010).

⁹ M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007).

at the same time as, or not long after, vaccination – and they do so even without knowing the medical (or legal) implications of their contention.

There is also a lack of any mention of left shoulder pain at multiple treater visits in November 2018. Although many such visits were not necessarily instances in which shoulder pain would be reported, they at least demonstrate Petitioner would seek treatment for problems she was encountering – suggesting shoulder pain should also have prompted a doctor's visit. And she only described a close-in-time onset when seen by a new orthopedist in late August 2019 – more than a year post-vaccination. *Compare* Exhibit 8 at 65-68; Exhibit 5 at 28-36; Exhibit 6 at 26-28 *with* Exhibit 7 at 36.

The rationale Petitioner provided in her first signed declaration for this failure to report onset consistent with the Table sooner is contradicted by other evidence. See Exhibit 17 at ¶ 5. It is illogical to believe that Petitioner would have reported a seemingly minor concern – of mild swelling in her ankles indicated by an indentation from her sock, during her November 2018 visit to her PCP, for example - without *also* mentioning the significant left shoulder pain Petitioner, her husband, and her children later claimed she was experiencing during this time. See Exhibit 8 at 65.

Later-provided histories (mostly contained in witness statements prepared for this case) have reasonably been given less weight. It is natural for individual's memories to fade over time, and for events to become confused with the passage of time. Thus, the descriptions provided by Petitioner and her family members, several years post-vaccination, of events that occurred in 2018 and 2019, are not sufficient to counter the consistent information regarding onset which can be found in the contemporaneously-created medical records.

Petitioner has maintained that records that do not corroborate her onset allegations are incorrect. To that end, she sought revised medical records from two of these providers which conform to her later allegations. See Exhibits 14-15. However, there is no evidence showing these alterations were based upon reliable evidence such as *other documentation* maintained by these providers, or their shared recollections of these events. Indeed - at least one provider refused to make the requested adjustment because the change could not be verified. See Exhibit 16 at 2.

Overall, the record in this case better supports a finding that the onset of Petitioner's left shoulder pain developed in late November or early December 2018, several months post-vaccination. She was noted as experiencing intermittent pain during this time. Exhibit 8 at 81. The record as a whole does not support Petitioner's assertion of a pain beginning the night of August 9th, or even within 48 hours of vaccination as first

alleged. Petitioner has thus failed to provide evidence to establish the onset required for a Table SIRVA injury.

VI. Potential for Off-Table Claim

A petitioner's failure to establish a Table injury does not necessarily constitute the end of a case under all circumstances, because he or she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. See *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009)).

Here, however, any causation-in-fact claim cannot proceed unless Petitioner can offer some evidence of causation consistent with my finding regarding onset. She must establish a causal link and appropriate time frame between the vaccination she received in August 2018 and pain which developed several months later, in late November or early December.

At this point, the only evidence Petitioner has submitted which might support a causation-in-fact claim – the opinion of the second orthopedist she saw in August 2019 and later - relies upon Petitioner's assertion that she had suffered her left shoulder pain since the time of vaccination, rather than later. See Exhibit 13 (letter from this second orthopedist); Exhibit 7 at 1-11 (first visit to this second orthopedist). But as shown by the handout and medical literature Petitioner supplied, an onset of pain very close in time to vaccination is key to a SIRVA diagnosis. Exhibit 17 at 7 (handout citing the Atanasoff article); Exhibit 28 at 2 (Atanasoff article). Almost all individuals suffering a SIRVA injury experienced pain within 24 hours of vaccination, with approximately 50 percent experiencing immediate pain. *Id.*

Although it is logical for the second orthopedist to have opined about causation based upon the information he believed to be correct, treater opinions do not receive evidentiary weight in the Program when they are based on incorrect facts. Rather, for any treating physician opinion to be credible, it must be shown to be based upon all relevant evidence in this case, including Petitioner's complete medical records - unrevised and revised versions. This also includes fact rulings made in the case.

As it presently stands, then, this treater opinion lacks probative value since it relies on an assumption the present fact ruling rejects. If Petitioner wishes to proceed on a causation-in-fact claim, she must provide *some* evidence showing that the left shoulder pain she experienced in the fall of 2018 and later was caused by the Tdap vaccine she

received in August 2018 – and that a SIRVA-like injury could so arise even if several months after vaccination. Otherwise, the entire petition will be dismissed.

VII. Conclusion

Petitioner has not established the onset of her left shoulder pain occurred within 48 hours of her receipt of the Tdap vaccine on August 9, 2018. Accordingly, her Table SIRVA claim is DISMISSED.

Before I provide the final ruling on the record requested by Petitioner, I will allow her an opportunity to provide evidence to support a causation-in-fact claim, such as a properly informed opinion of a treating physician. If Petitioner wishes to continue with her causation-in-fact claim, she will need to provide sufficient additional evidence to justify allowing the matter to go on.

Petitioner is hereby ORDERED to file other evidence needed to establish that the Tdap vaccine she received on August 9, 2018, caused her left shoulder pain which began several months later, or to Show Cause why this case should not be dismissed for insufficient evidence, by Friday, September 2, 2022.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master